



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,510	06/07/2000	Pramod B. Mahajan	1121	9021

27310 7590 06/17/2003

PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
----------	--------------

1638

20

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/589,510

Applicant(s)

MAHAJAN, PRAMOD B.

Examiner

Medina A Ibrahim

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9 and 14-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,16,17 and 20-28 is/are rejected.
- 7) ☒ Claim(s) 14-15 and 18-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 03/31/03 in reply to the Office action mailed 12/03/02 and amendment E have entered. Claims 1, 3-9 and 14-28 are pending and are under examination.

All previous rejections and objections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1, 3-9, 17 and 20-28 are rejected under 35 U.S.C. 112, **first paragraph**, because the specification, while being enabling for the isolated nucleic acid sequence of SEQ ID NO: 3 or a polynucleotide encoding SEQ ID NO: 4 and transgenic plant, plant cell and seed comprising said sequence, does not reasonably provide enablement for any isolated nucleic acid sequence having at least 90% sequence identity to SEQ ID NO: 3 and encoding a polypeptide having RuvB activity and transgenic plant/ plant cell/seed comprising them. This rejection is repeated for the reasons of record as set forth in the Office action mailed 12/13/2002. Applicant's arguments filed 03/31/03 have been considered but are not deemed persuasive.

Applicant argues that the claimed nucleic acid sequence having at least 90% sequence identity to SEQ ID NO: 3 and encoding a polypeptide having RuvB activity is enabled, given the guidance provided in the instant specification and the teachings of the prior art. Applicant contends that all that is required for DNA sequences is to disclose how to make and use enough sequences to justify grant of the claims sought

Art Unit: 1638

for protection. Applicant believes that has been done in the instant specification. Applicant asserts that given the disclosure of SEQ ID NO: 1-10, the conserved domains and motifs shown in Example 4, the sequence identity and similarity to other known RuvB sequences, the guidance on sequence analysis, guidance on genetic code degeneracy or silent variants and conservative amino acid substitutions, and guidance on methods on isolating and testing sequences for RuvB activity, one skilled in the art will be able to make sequences having 90% identity to SEQ ID NO: 3 and encoding a polypeptide having RuvB activity, and use them for the production of transgenic plants/plant cells and seed with a desired trait. Applicant finally argues that, given the guidance provided in the instant specification and what is known in the art, the amount of experimentation required to practice the claimed invention is merely routine. Applicant urges that the rejection be withdrawn.

Contrary to Applicant's arguments the claimed invention is not supported by an enabling disclosure for the reasons of record. The 35 USC 112, 1st and supporting case laws do not require that Applicant exemplifies all nucleic acid sequences having at least 90% sequence identity to SEQ ID NO: 3 and encoding a polypeptide having RuvB activity. However, as agreed by Applicant, the disclosure must contain sufficient guidance to enable any person skilled in the art to carry out the invention commensurate with scope of the claims. That has not been done in the instant specification. The specification discloses unmodified sequences and merely provides guidance on methods for altering single amino acid or conservative amino acid substitutions in given nucleotide/protein sequence to produce variants. For example, on

Art Unit: 1638

pages 8 and 9 of the specification, Applicant discusses about conservatively modified nucleic acid variants or silent variants that encode identical or conservatively modified variants of the amino acid sequences. However, according to Lazar et al disclosed in last Office action, conserved amino acid substitutions may not result in predictable results. Lazar showed that the conservative substitution of glutamic acid for aspartic acid at position 47 changed the biological function of transforming growth factor-alpha, while non-conservative substitutions with alanine or asparagine had no effect. Therefore, without specific guidance as to which modifications would allow SEQ ID NO: 3 retain both the structural and functional limitations as recited in the, one cannot predict whether any and all with nucleic acid sequences having at least 90% sequence identity to SEQ ID NO: 3 would encode a polypeptide having RuvB activity.

With respect to the sequences of SEQ ID NO: 1, 5, 7 and 9 that share from 87.2% to 97.6% sequence identity to SEQ ID NO: 3, it is noted that while these variants meet both the claimed structural and functional limitations, the claimed nucleic acid variants are not limited to maize variants but encompass all nucleic acid sequences from any source having 90% sequence identity to the disclosed sequence. Therefore, Applicant's argument is not deemed persuasive.

Therefore, in view of the reasons discussed above and in the last Office action, the claimed invention is not enabled throughout the broad scope.

Written Description

Claims 16 and 28 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

Art Unit: 1638

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the Office action mailed 12/03/2002. Applicant's arguments filed 03/31/03 have been fully considered but are not deemed persuasive.

Applicant argues that the specification describes other nucleic acid sequences, SEQ ID NO: 1, 5, 7, and 9, which comprise at least 100 contiguous bases of SEQ ID NO: 3 or encoding a polypeptide comprising at least 50 contiguous amino acids of SEQ ID NO: 4. Applicants assert that the disclosed sequences are sufficient to provide adequate written description of the claimed genus.

Applicant's arguments are not persuasive for two main reasons: firstly, the claims are not limited to nucleic acid variants from maize but encompass variants from all sources including maize. Secondly, a substantial variation in structures and in function is expected among nucleic acid sequences that share any 100 contiguous bases of SEQ ID NO: 3 or encode polypeptides that share any 50 contiguous amino acids of SEQ ID NO: 4. Therefore, the disclosed sequences are not representative species of the claimed genus. Therefore, the disclosure of SEQ ID NO: 1, 3, 5, 7 and 9 from maize is sufficient to provide adequate written description of the claimed genus, isolated polynucleotides comprising at least 100 contiguous bases of SEQ ID NO: 3 or encoding a polypeptide comprising at least 50 contiguous amino acids of SEQ ID NO: 4.

Remarks

Claims 1, 3-9 and 14-28 are free of the prior art of record.

Art Unit: 1638

Claims 14-15 and 18-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

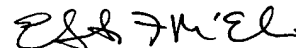
Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

6/11/03
Mai


ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800